TITLE 180 CONTROL OF RADIATION

CHAPTER 6 DIAGNOSTIC X-RAYS OTHER THAN DENTAL RADIATION GENERATING EQUIPMENT IN THE HEALING ARTS

APPENDIXES

ATTTACHMENTS

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TITLE 180 CONTROL OF RADIATION

CHAPTER 6 DIAGNOSTIC X-RAYS OTHER THAN DENTAL RADIATION GENERATING EQUIPMENT IN THE HEALING ARTS

6-001 SCOPE AND AUTHORITY

6-001.01 180 NAC 6 establishes requirements, for which a registrant is responsible, for use of diagnostic x-ray equipment and imaging systems by or under the supervision of an individual `authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 3520.

6-001.02 The use of x-ray equipment for the intentional exposure of individuals for diagnosis or treatment must be by or under the supervision of one licensed to practice the healing arts in Nebraska.

6-001.03 The use of x-ray equipment in the practice of veterinary medicine must be by or under the supervision of an individual licensed to practice veterinary medicine in the State of Nebraska.

6-001.04 The provisions of 180 NAC 6 are in addition to, and not in substitution for, other applicable provisions of 180 NAC 1, 2, 4, 9, 10, 15, 16, 17, 18 and 20.

6-002 DEFINITIONS: As used in Title 180, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Added filtration means any filtration which is in addition to the inherent filtration.

Aluminum equivalent means the thickness of type 1100 aluminum alloy[1] affording the same attenuation, under specified conditions, as the material in question.

Attenuation block means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[2] or other materials having equivalent attenuation.

[1]The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, maximum 0.12 percent copper.

[2]Ibid.

Automatic exposure control (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (Includes devices such as phototimers and ion chambers).

Barrier (See "Protective barrier").

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device that provides a means to restrict the dimensions of the x-ray field.

Bone densitometry systems means a medical device which uses electronically-produced ionizing radiation to determine the density of bone structures of human patients.

C-arm x-ray system means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

Certified components means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, the Food and Drug Administration because they come within the definitions in Section 355 (1) and (2) of that law, attached hereto as Attachment Number 6-1 and incorporated herein by this reference.

Certified system means any x-ray system which has one or more certified component(s).

Coefficient of variation or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}\left(x_1 - \bar{x}\right)^2}{n-1}\right]^{1/2}$$

where

s = Estimated standard deviation of the population.
X = Mean value of observations in sample.
X_i = i^{th} observation in sample.
n = Number of observations in sample.

Computed tomography means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, push-buttons, and other hardware necessary for manually setting the technique factors.

Cooling curve means the graphical relationship between heat units stored and cooling time.

CT (See "Computed tomography").

Deadman switch means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Detector (See Radiation detector).

Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Direct scattered radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered radiation").

Entrance exposure rate means the exposure free in air per unit time.

Equipment (See "X-ray equipment").

Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter means material placed in the useful beam to preferentially absorb selected radiations.

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a visible image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Focal spot (actual) means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

General purpose radiographic x-ray system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Gonad shield means a protective barrier for the testes or ovaries.

Half-value layer means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Healing arts screening means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Heat unit means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

HVL (See "Half-value layer").

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

Inherent filtration means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Interpretative Fluoroscopic Procedures, for the purpose of these regulations, means the use of radiation in continuous mode to provide information, data and film or hardcopy images for diagnostic review and interpretation by a licensed practitioner as the images are being produced.

Irradiation means the exposure of matter to ionizing radiation.

Kilovolts peak (See "Peak tube potential").

kV means kilovolts.

kVp (See Peak tube potential).

Lead equivalent means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation means radiation emanating from the diagnostic or therapeutic source assembly except for:

1. the useful beam; and
2. radiation produced when the exposure switch or timer is not activated.

Leakage technique factors means the technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows:

1. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an

hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger.

2. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

3. For all other diagnostic or therapeutic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

mA means milliampere.

mAs means milliampere second.

Mobile x-ray equipment (See X-ray equipment).

Patient means an individual subjected to healing arts examination, diagnosis, or treatment.

PBL (See Positive beam limitation)

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Phantom means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

Portable x-ray equipment (See X-ray equipment).

Positive beam limitation means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposure cannot be made without such adjustment.

Primary protective barrier (See Protective barrier).

Protective apron means an apron made of radiation absorbing materials used to reduce radiation exposure.

Protective barrier means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

Primary protective barrier means the material, excluding filters, placed in the useful beam;

Secondary protective barrier means a barrier sufficient to attenuate the stray radiation to the required degree.

Protective glove means a glove made of radiation absorbing materials used to reduce radiation exposure.

Qualified expert means an individual who meets the requirements of 180 NAC 15-013.03.

Radiation detector means a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation therapy simulation system means a fluoroscopic or radiographic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiograph means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Radiological medical physicist means an individual who meets the requirements of 180 NAC 15-013.02.

Recording means producing a permanent form of an image resulting from x-ray photons.

Scattered radiation means radiation that, during passage through matter, has been deviated in direction (See "Direct scattered radiation").

Secondary protective barrier (See "Protective barrier").

Shutter means a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SID (See Source-image receptor distance).

Source means the focal spot of the x-ray tube.

Source-image receptor distance means the distance from the source to the center of the input surface of the image receptor.

Spot film means a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

SSD means the distance between the source and the skin of the patient.

Stationary x-ray equipment (See X-ray equipment).

Stray radiation means the sum of leakage and scattered radiation.

Technique factors means the conditions of operation. They are specified as follows:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

2. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

3. For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

4. For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

5. For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Tomogram means the depiction of the x-ray attenuation properties of a section through the body.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

Visible area means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

X-ray exposure control means a device, switch, button or other similar means by which an operator initiates and/or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timer and back-up timers.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

Mobile x-ray equipment means x-ray equipment which is designed to be mounted on a permanent base with wheels and/or casters for moving while completely assembled.

Portable x-ray equipment means x-ray equipment designed to be hand-carried.

Stationary x-ray equipment means x-ray equipment which is designed to be installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray system means an assemblage of components for the controlled production of x-rays, including, but not limited to, an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray tube means any electron tube which is designed to be used primarily for the production of x-rays.

6-003 GENERAL REQUIREMENTS

6-003.01 Administrative Controls

1. Registrant: The registrant must be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent must assure that the requirements of 180 NAC 6-003.01, item 1. are met in the operation of the x-ray system(s).

    a. An x-ray system which does not meet the provisions of Title 180 must not be operated for diagnostic purposes.
    b. Registrants must assure that individuals who will operate x-ray systems under the direction of healing arts practitioners must meet the requirements as specified in 180 NAC 16.

c. A chart must be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:

(1) Patient's body part and anatomical size, or body part thickness, or age (for pediatrics) versus technique factors to be utilized;
(2) Type and focal distance of the grid to be used, if any;
(3) Source to image receptor distance to be;
(4) Type and location of placement of gonad shielding to be used; and
(5) Type and size of the film or film-screen combination to be used.

d. The registrant of a facility must create and make available to x-ray operators written safety procedures, including patient holding and any restriction of the operating technique required for the safe operation of the particular x-ray system. The operator must be able to demonstrate familiarity with these procedures:

(1) Doors that are an integral part of room shielding must be closed during x-ray procedures; and
(2) The door in 180 NAC 6-003.01, item 1.d.(1) be posted "Close door during x-ray procedures".

e. Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training may be in the room during the radiographic exposure. Other than the patient being examined:

(1) All individuals must be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent.
(2) The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure must be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.
(3) Patients who cannot be removed from the room must be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent or must be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

f. Gonad shielding of not less than 0.25 millimeter lead equivalent must be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

g. Individuals must not be exposed to the useful beam except for healing arts purposes and unless such exposure has been specially and individually ordered by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

(1) Exposure of an individual for training, demonstration, or other non-healing-arts purposes; and
(2) Exposure of an individual for the purpose of healing arts screening except as authorized by 180 NAC 6-003.01, item 1. k.

h. When a patient or film must be provided with auxiliary support during a radiation exposure:

(1) Mechanical holding devices must be used when the technique permits. The written safety procedures, required by 180 NAC 6-003.01, item 1., d., must list projections where holding devices cannot be utilized;
(2) The human holder must be instructed in personal radiation safety and protected as required by 180 NAC 6-003, item 1. e.;
(3) No individual must be used routinely to hold film or patients;
(4) Written safety procedures, as required by 180 NAC 6-003.01, item 1. d.; must indicate the requirements for selecting a holder and the procedure the holder must follow; and
(5) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam must be protected by not less than 0.5 millimeter lead equivalent material.
(6) Each facility must have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.

i. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information must be utilized.

(1) The speed of film or screen and film combinations must be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens must not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography.
(2) The radiation exposure to the patient must be the minimum exposure required to produce images of good diagnostic quality.
(3) X-ray systems subject to 180 NAC 6-006 must not be utilized in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems.
(4) If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid must:

(a) Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray;
(b) If the grid is of the focused type, be of the proper focal distance for the SIDs being used.

j. All individuals who are associated with the operation of an x-ray system are subject to the requirements of 180 NAC 4-005, 4-022, and 4-050. In addition:

(1) When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such monitoring device must be utilized as follows:

(a) When an apron is worn, the monitoring device must be worn at the collar outside the apron.
(b) The dose to the whole body based on the maximum dose attributed to the most critical organ must be recorded in the reports required by 180 NAC 4-052. If more than one device is used and a record is made of the data, each dose must be identified with the area where the device was worn on the body.
(c) When portable or mobile x-ray equipment is utilized, a personnel monitoring device must be worn.

(2) Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

k. Healing Arts Screening: Any person proposing to conduct a healing arts screening program must not initiate such a program without prior approval of the Department. When requesting such approval, that person must submit the information outlined in Appendix A of 180 NAC 6. If any information submitted to the Department becomes invalid or outdated, the Department must be immediately notified.

2. Information and Maintenance Record and Associated Information: The registrant must maintain the following information for each x-ray system for inspection by the Department:

a. Model and serial numbers of all certifiable components, and user's manuals for those components;
b. Tube rating charts and cooling curves;
c. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system(s); and
d. A scale drawing must be available of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to

the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing must include:

(1) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or
(2) The type and thickness of materials, or lead equivalency, of each protective barrier; and

e. A copy of all correspondence with this Department regarding that x-ray system.

6-003.02 X-ray Utilization Log Each facility must maintain an x-ray log or chart containing the patient's name, the type of examinations, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder must be recorded.

6-003.03 Plan Review, Other Than Facilities Using Only Bone Densitometers

1. The floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing x-rays must be submitted to a qualified expert for review and comment. The required information is denoted in Appendix B of 180 NAC 6.

2. The review of such plans does not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 180 NAC 4-005, 4-011 and 4-013.

6-003.04 X-ray Film Processing Facilities and Practices

1. Each installation using a radiographic x-ray system and using analog image receptors (e.g. radiographic film) must have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

a. Manually developed film:

(1) Processing tanks must be constructed of mechanically rigid, corrosion resistant material; and
(2) The temperature of solutions in the tanks must be maintained within the range of 60^{o} F to 80^{o} F (16^{o} C to 27^{o} C). Film must be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2½
25.0	77	2½
24.4	76	3
23.9	75	3
23.3	74	3½
22.8	73	3½
22.2	72	4
21.7	71	4
21.1	70	4½
20.6	69	4½
20.0	68	5
19.4	67	5½
18.9	66	5½
18.3	65	6
17.8	64	6½
17.2	63	7
16.7	62	8
16.1	61	8½
15.6	60	9½

(3) Devices must be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

b. Automatic processors and other closed processing systems:

(1) Films must be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film must be developed using the following chart:

Developer Temperature		Minimum Immersion Time[a/]
°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30
[a/] *Immersion time only, no crossover time included.*		

(2) The specified developer temperature and development time must be posted in the darkroom or on the automatic processor.

c. Processing deviations from the requirements of 180 NAC 6-003.04 item 1 must be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

2. Other Requirements.

a. The darkroom must be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed must not suffer an increase in density greater than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes must preclude fogging of the film.

b. Film must be stored in a cool, dry place and must be protected from exposure to stray radiation. Film in open packages must be stored in a light tight container.

c. Film cassettes and intensifying screens must be inspected periodically and must be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

d. Outdated x-ray film must not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations.

e. Film developing solutions must be prepared in accordance with the directions given by the manufacturer, and must be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

6-004 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC X-RAY SYSTEMS: In addition to other requirements of 180 NAC 6-004 all diagnostic x-ray systems must meet the following requirements:

6-004.01 Warning Label: The control panel containing the main power switch must bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

6-004.02 Battery Charge Indicator: On battery-powered x-ray generators, visual means must be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

6-004.03 Leakage Radiation from the Diagnostic Source Assembly: The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source must not exceed 25.8 uC/kg(100 milliroentgens) in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance must be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-004.04 Radiation from Components Other Than the Diagnostic Source Assembly: The radiation emitted by a component other than the diagnostic source assembly must not exceed 0.5C/kg (2 milliroentgens) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance must be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-004.05 Beam Quality

1. Half-value Layer

a. The half-value layer of the useful beam for a given x-ray tube potential must not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

TABLE I		
Design Operating Range	Measured Potential (kVp)	Half-Value Layer In mm Aluminum
		All Other Diagnostic X-Ray Systems
Below 51	30	0.3
	40	0.4
	50	0.5
51 to 70	51	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

b. For capacitor energy storage equipment, compliance with the requirements of 180 NAC 6-004.05 must be determined with the maximum quantity of charge per exposure.

c. The required minimal aluminum equivalent filtration must include the filtration contributed by all materials which are always present between the source and the patient.

2. Filtration Controls: For x-ray systems which have variable kVp and variable filtration for the useful beam, a device must link the kVp selector with the filter(s) and must prevent an exposure unless the minimum amount of filtration required by 180 NAC 6-004.05, item 1.a. is in the useful beam for the given kVp which has been selected.

6-004.06 Multiple Tubes: Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected must be clearly indicated prior to initiation of the exposure. This indication must be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

6-004.07 Mechanical Support of Tube Head: The tube housing assembly supports must be adjusted such that the tube housing assembly will remain stable during the exposure unless the tube housing movement is a designed function of the x-ray system.

6-004.08 Technique Indicators

1. The technique factors to be used during an exposure must be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure must be indicated.

2. The requirement of 180 NAC 6-004.08, item 1. may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors must be visible from the operator's position except in the case of spot films made by the fluoroscopist.

6-004.09 Maintaining Compliance: Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-ray Equipment Performance Standard (21 CFR Part 1020) must be maintained in compliance with applicable requirements of that standard.

6-004.10 Locks: All position locking, holding, and centering devices on x-ray system components and systems must function as intended.

6-004.11 Equipment Performance Evaluation: For all radiation generating equipment, except Bone Densitometry , Veterinary and Computed Tomography (CT), the registrant must perform or cause to be performed, tests necessary to insure the proper function of equipment and a measurement of the in air exposure(s) at the technique factor(s) for an average adult thickness for routine procedures preformed at the facility. At a minimum these tests must be at least performed every three years and must include:

1. Timer:

   a. The accuracy of the timer must meet the manufacturer's specifications. If the manufacturer's specifications are not obtainable, the timer accuracy must be ±10% of the indicated time with testing performed at 0.5 second.
   b. Means must be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it must not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

2. Exposure Reproducibility: When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems will not exceed 0.05.

3. Kilovolt Peak: If the registrant possesses documentation of the appropriate manufacturer's kilovolt peak specifications, the radiation machine must meet those specifications. If the registrant does not possess documentation of the appropriate manufacturer's kilovolt peak specifications, the indicated kilovolt peak must be accurate to within ± 10% of the indicated setting(s).

4. Tube Stability: The x-ray tube must remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant will assure proper and free movement of the radiation generating equipment.

5. Collimation: Field limitation must meet the requirements of 180 NAC 6-005.01, item 2 and 6-006.01, item 1.

6-005 FLUOROSCOPIC X-RAY SYSTEMS: Use of nonimage intensified fluoroscopic equipment is prohibited. All fluoroscopic x-ray systems must meet the following requirements:

6-005.01 Limitation of Useful Beam

1. Primary Barrier

   a. The fluoroscopic imaging assembly must be provided with a primary protective barrier which intercepts the entire cross-section of the useful beam at any SID.
   b The x-ray tube used for fluoroscopy must not produce x-rays unless the barrier is in position to intercept the entire useful beam.

2. Fluoroscopic Beam Limitation

   a. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor must exceed that of the visible area of the image receptor by more than 3 per-cent of

the SID. The sum of the excess length and the excess width must be no greater than 4 percent of the SID.

b. For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) must be no larger than the largest spot film size for which the device is designed. Measurements must be made at the maximum SID available but at no less than 20 centimeters table top to the film plane distance.

c. For uncertified fluoroscopic systems without a spot film device, the requirements of 180 NAC 6-005.01, item 1.a. apply.

d. Other requirements for fluoroscopic beam limitation:

(1) Means must be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than 300 square centimeters must be provided with means for stepless adjustment of the x-ray field;

(2) All equipment with a fixed SID and a visible area of 300 square centimeters or less must be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less.

(3) Stepless adjustment must, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 by 5 centimeters or less;

(4) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor; and

(5) For non-circular x-ray fields used with circular image receptor, the error in alignment must be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

3. Spot-film Beam Limitation. Spot-film devices must meet the following requirements:

a. Means must be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment must be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size must be only at the operator's option;

b. Neither the length nor the width of the x-ray field in the plane of the image receptor must differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to size, of the length and width differences must not exceed 4 percent of the SID;

c. It must be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID must be equal to, or less than, 5 centimeters by 5 centimeters;
d. The center of the x-ray field in the plane of the film must be aligned with the center of the selected portion of the film to within 2 percent of the SID; and
e. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance must be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

4. Override: If a means exists to override any of the automatic x-ray field size adjustments required in 180 NAC 6-005.01, item 2 or 3, that means:

a. Must be designed for use only in the event of system failure;
b. Must incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and
c. Must be clearly and durably labeled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

6-005.02 Activation of the Fluoroscopic Tube: X-ray production in the fluoroscopic mode must be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist must be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

6-005.03 Exposure Rate Limits

1. Entrance Exposure Rate Allowable Limits

a. Fluoroscopic equipment which is provided with automatic exposure rate control must not be operable at any combination of tube potential and current which will results, in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(1) During recording of fluoroscopic images; or
(2) When an optional high level control is provided. When so provided. The equipment must not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls is be required. The high level control must only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist must indicate that the high level control is being employed.

b. Fluoroscopic equipment which is not provided with automatic exposure rate control must not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.29 mC/kg) per minute at the point where the useful beam enters the patient except:

(1) During recording of fluoroscopic images; or
(2) When an optional high level control is activated. Special means of activation of high level controls is required. The high level control must only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist must indicate that the high level control is being employed.
.

c. Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode must not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute in either mode at the point where the center of the useful beam enters the patient, except:

(1) During recording of fluoroscopic images; or
(2) When the mode or modes have an optional high level control, in which case that mode or modes must not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls is required. The high level control must only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist must indicate that the high level control is being employed.

d. Any fluoroscopic equipment manufactured after May 19, 1995, which can exceed 1.3 mC/kg (5 roentgens) per minute are equipped with an automatic exposure rate control. Entrance exposure rate limits must be 2.6 mC/kg (10 roentgens) per minute with an upper limit of 5.2 mC/kg (20 roentgens) per minute when high level control is activated.

e. Compliance with the requirements of 180 NAC 6-005.03 must be determined as follows:

(1) If the source is below the x-ray table, the exposure rate must be measured 1 centimeter above the tabletop or cradle;
(2) If the source is above the x-ray table, the exposure rate must be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;
(3) For a C-arm type of fluoroscope, the exposure rate must be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly,

with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;

(4) For a lateral type fluoroscope, the exposure rate must be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it must be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

2. Periodic measurement of entrance exposure rate must be performed by a qualified expert for both typical and maximum values as follows:[3/]

a. Such measurements must be made annually or after any maintenance of the system which might affect the exposure rate;

b. Results of these measurements must be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in 180 NAC 6-003.01 item 2.c. The measurement results must be stated in coulombs per kilogram (roentgens) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed must be included in the results;

c. Conditions of periodic measurement of typical entrance exposure rate are as follows:

(1) The measurement must be made under the conditions that satisfy the requirements of 180 NAC 6-005.03 item 1. e.;

(2) The kVp, mA, and/or other selectable parameters must be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;

(3) The x-ray system that incorporates automatic exposure rate control must have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of 180 NAC 6-005.03, item 2.c.(2);

(4) Conditions of periodic measurement of maximum entrance exposure rate are as follows:

(a) The measurement must be made under the conditions that satisfy the requirements of 180 NAC 6-005.03, item 1.d.

(b) The kVp, mA and/or other selectable parameters must be adjusted to those settings which give the maximum entrance exposure rate;

(c) The x-ray system(s) that incorporates automatic exposure control must have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

[3/] Materials should be placed in the useful beam to protect the imaging system when conducting these periodic measurements.

6-005.04 Barrier Transmitted Radiation Rate Limits

1. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, must not exceed 0.5 μC/kg (2 milliroentgens) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mC/kg (roentgen) per minute of entrance exposure rate.

2. Measuring Compliance of Barrier Transmission

   a. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier must be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
   b. If the source is below the tabletop, the measurement must be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.
   c. If the source is above the tabletop and the SID is variable, the measurement must be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it must not be closer than 30 centimeters.
   d. Movable grids and compression devices must be removed from the useful beam during the measurement.

6-005.05 Indication of Potential and Current: During fluoroscopy and cinefluorography, the kV and the mA must be continuously indicated and must not exceed the maximum deviation as stated by the manufacturer.

6-005.06 Source-to-Skin Distance: The SSD must not be less than:

1. 38 centimeters on stationary fluoroscopes installed after November 23, 1990,

2. 35.5 centimeters on stationary fluoroscopes which were in operation prior to November 23, 1990,

3. 30 centimeters on all mobile fluoroscopes, and

4. 20 centimeters for image intensified fluoroscopes used for specific surgical application.

6-005.07 Fluoroscopic Timer

1. Means must be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device must not exceed 5 minutes without resetting.

2. A signal audible to the fluoroscopist must indicate the completion of any preset cumulative on-time. Such signal must continue to sound while x-rays are produced until the timing device is reset.

3. The total time of exposure must be recorded.

6-005.08 Control of Scattered Radiation

1. Fluoroscopic table designs when combined with procedures utilized must be such that no unprotected part of any staff or ancillary individual's body can be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required must be not less than 0.25 millimeter lead equivalent.

2. Equipment configuration when combined with procedures must be such that no portion of any staff or ancillary individual's body, except the extremities, can be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

   a. Is at least 120 centimeters from the center of the useful beam, or
   b. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains in addition to any lead equivalency provided by the protective apron referred to in 180 NAC 6-003.01, item 1.e.

3. The Department may grant exceptions to 180 NAC 6-005.08, item 2., where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Department will not permit such exception. See Appendix 6-C for a suggested list of fluoroscopic procedures where such exemptions will be automatically granted.

6-005.09 Spot Film Exposure Reproducibility: Fluoroscopic systems equipped with spot film (radiographic) mode must meet the exposure reproducibility requirements of 180 NAC 6-006.04 when operating in the spot film mode.

6-005.10 Fluoroscopic Radiation Therapy Simulation Systems: Fluoroscopic radiation therapy simulation systems must be exempt from all the requirements of 180 NAC 6-005.03. In addition, these systems are exempt from the requirements of 180 NAC 6-005.01 and 6-005.04 provided such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays.

6-005.11 Equipment Operation

1. All imaging formed by the use of fluoroscopic x-ray systems must be under the direction of and interpreted by a licensed practitioner of the healing arts.

2. Only a licensed practitioner can perform interpretative fluoroscopic procedures.

3. Overhead fluoroscopy must not be used as a positioning tool for general purpose radiographic examinations.

4. Facilities must maintain a record of the cumulative fluoroscopic exposure time used and the number of fluorographic images recorded for each examination. This record must include patient identification, type and date of examination, the fluoroscopic system used, and operator's name.

6-006 RADIOGRAPHIC SYSTEMS OTHER THAN FLUOROSCOPIC, BONE DENSITOMETRY, VETERINARIAN, OR COMPUTED TOMOGRAPHY X-RAY SYSTEMS:

6-006.01 Beam Limitation, Except Mammographic Systems: The useful beam must be limited to the area of clinical interest.

1. General Purpose Stationary and Mobile X-Ray Systems

   a. Only x-ray systems provided with means for independent stepless adjustment of at least two dimensions of the x-ray field must be used.
   b. A method must be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field must not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

2. Additional Requirements for Stationary General Purpose X-Ray Systems: In addition to the requirements of 180 NAC 6-006.01, item 1., stationary general purpose x-ray systems, both certified and noncertified, must meet the following requirements:

   a. A method must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;
   b. The beam-limiting device must indicate numerically the field size in the plane of the image receptor to which it is adjusted; and
   c. Indication of field size dimensions and SID's must be specified in inches and/or centimeters, and must be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

3. X-Ray Systems Designed for One Image Receptor Size: Radiographic equipment designed for only one image receptor size at a fixed SID must be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or must be provided with means to

both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

4. X-Ray Systems Other Than Those Described in 180 NAC 6-006.01, item 1, 2 and 3

a. Means must be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

b. Means must be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means must be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

c. 180 NAC 6-006.01, item 5.a. and b. may be met with a system that meets the requirements for a general purpose x-ray system as specified in 180 NAC 6-006.01, item 1. or, when alignment means are also provided, may be met with either:

(1) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(2) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings must indicate the image receptor size and SID for which each aperture is designed and must indicate which aperture is in position for use.

6-006.02 Radiation Exposure Control

1. Exposure Initiation: Means must be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure must not be initiated without such an action. In addition, it must not be possible to initiate an exposure when the timer is set to a “zero” or ”off” position if either position is provided.

2. Exposure Indication: Means must be provided for visual indication observable at or from the operator’s protected position whenever x-rays are produced. In addition, a signal audible to the operator must indicate that the exposure has terminated.

3. Exposure Termination: Means must be provided to terminate the exposure at a preset time interval, preset product of current time, a preset number of pulses, or a preset radiation exposure to the image receptor.

a. Manual Exposure Control: An x-ray control must be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

(1) Exposure of ½ second or less; or
(2) During serial radiography when means must be provided to permit completion of any single exposure of the series in process.

b. Automatic Exposure Controls: When an automatic exposure control is provided:

(1). Indication must be made on the control panel when this mode of operation is selected;
(2) If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation must be equal to or less than a time interval equivalent to two pulses;
(3) The minimum exposure time for all equipment other than that specified in 180 NAC 6-006.02, item 3.b. must be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;
(4) Either the product of peak x-ray tube potential, current, and exposure time must be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time must be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time must be limited to not more than 2000 mAs per exposure; and
(5) A visible signal must indicate when an exposure has been terminated at the limits required by 180 NAC 6-006.02, item 3.d. and manual resetting must be required before further automatically timed exposures can be made.

4. Exposure Duration (Timer) Linearity: For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings must not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

5. Exposure Control Location: The x-ray exposure control must be so placed that the operator can view the patient while making any exposure.

6. Operator Protection: Stationary x-ray systems must be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

6-006.03 Source-to-Skin Distance: All mobile or portable radiographic systems must be provided with means to limit the source-to-skin distance to greater than or equal to 30 centimeter.

6-006.04 Exposure Reproducibility: When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems must not exceed 0.05. This requirement applies to clinically used technique.

6-006.05 Radiation from Capacitor Energy Storage Equipment in Standby Status: Radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated must not exceed a rate of 0.5 μC/kg (2 milliroentgens) per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

6-006.06 Accuracy: Deviation of measured technique factors from indicated values of kVp and exposure time must not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation must not exceed 10 percent of the indicated value for kVp and 10 percent for time.

6-006.07 mA/mAs Linearity: The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

1. Equipment Having Independent Selection of X-Ray Tube Current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product (C kg^{-1} mAs^{-1} (or mR/mAs)) obtained at any two consecutive tube current settings must not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

2. Equipment Having a Combined X-Ray Tube Current-Exposure Time Product (mAs) Selector, But Not a Separate Tube Current (mA) Selector: The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings must not differ by more than 0.10 times their sum:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two consecutive mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

3. Measuring Compliance: Determination of compliance must be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

6-006.08 Additional Requirements Applicable to Certified Systems Only: Diagnostic x-ray systems incorporating one or more certified component(s) must be required to comply with the following additional requirement(s) which relate to that certified component(s).

1. Beam Limitation for Stationary and Mobile General Purpose X-Ray Systems.

   a. There must be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters must be equal to or less than 5 centimeters by 5 centimeters.
   b. When a light localizer is used to define the x-ray field, it must provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination must be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.
   c. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, must have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance must be determined with a measuring instrument aperture of 1 millimeter in diameter.

2. Beam Limitation and Alignment on Stationary General Purpose X-Ray Systems Equipped with PBL. If PBL is being used, the following requirements must be met:

   a. PBL must prevent the production of x-rays when:

      (1) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by 180 NAC 6-006.08, item 2.c., from the corresponding image receptor dimensions by more than 3 percent of the SID; or
      (2) The sum of the length and width differences as stated in 180 NAC 6-006.08, item 2.a.(1) without regard to size exceeds 4 percent of the SID;

   b. Compliance with 180 NAC 6-006.08, item 2.a. must be determined when the equipment indicates that the beam axis is perpendicular to the plane of the

image receptor. Compliance must be determined no sooner than 5 seconds after insertion of the image receptor;

c. The PBL system must be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters must be equal to or less than 5 centimeters by 5 centimeters;

d. The PBL system must be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in 180 NAC 6-006.08, item 2.a., then any change of image receptor size or SID must cause the automatic return.

3. Beam Limitation for Portable X-Ray Systems. Beam limitation for portable x-ray systems must meet the beam limitation requirements of 180 NAC 6-006.01, item 1 and 180 NAC 6-006.08, item 1.

6-006.09 Tube Stands for Portable X-Ray Systems: A tube stand or other mechanical support must be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

6-007 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS

6-007.01 Equipment

1. The protective tube housing must be equivalent to the requirements of 180 NAC 6-004.03.

2. Diaphragms or cones must be provided for collimating the useful beam to the area of clinical interest and must provide the same degree of protection as is required of the housing.

3. The total filtration permanently in the useful beam must not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

4. A device must be provided to terminate the exposure after a preset time or exposure.

5. A dead-man type of exposure switch must be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet (1.83m) from the animal during all x-ray exposures.

6-007.02 Structural Shielding: All wall, ceiling, and floor areas must be equivalent to or provided with applicable protective barriers to assure compliance with 180 NAC 4-005, 4-011, and 4-013.

6-007.03 Operating Procedures

1. The operator must be protected from the direct scatter radiation by a whole body protective barrier of 0.25 millimeter lead equivalent or must be so positioned that the nearest portion of the body is at least 2 meters from the tube head and the nearest edge of the image receptor.

2. No individual other than the operator may be in the x-ray room while exposures are being made unless such individual's assistance is required.

3. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual must be protected with appropriate shielding devices, such as protective gloves and apron, and be so positioned that no part of the body will be struck by the useful beam.

6-07.04 Veterinary Assistant's Training Requirements: Veterinary assistant's must have:

1. Eight (8) hours of classroom instruction in the fundamentals of radiation safety, radiographic equipment, state regulations, and operating and emergency procedures or

2. Have graduated from an accredited veterinarian technicians program.

6-008 COMPUTED TOMOGRAPHY SYSTEMS

6-008.01 Definitions: In addition to the definitions provided in 180 NAC 1-002 and 180 NAC 6-002, the following definitions must be applicable to 180 NAC 6-008:

1. "Computed tomography dose index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\mathrm{CTDI} = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\, dz$$

where:

z = Position along a line perpendicular to the tomographic plane.
D(z) = Dose at position z.
T = Nominal tomographic section thickness.
n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

2. "CTDI" (See "Computed tomography dose index").

3. "Contrast scale" means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN}_x - \overline{CTN}_w}$$

where:

u_x = Linear attenuation coefficient of the material interest.
u_w = Linear attenuation coefficient of water.
$\overline{CTN}_x$ = CTN of the material of interest.
$\overline{CTN}_w$ = CTN of water.

4. "CS" (See "Contrast scale").

5. "CT conditions of operation" means all selectable parameters governing the operation of a CT system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 180 NAC 6-002.

6. "CTDI" (See "Computed tomography dose index").

7. "CT Gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

8. "CTN" (See "CT number").

9. "CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k(u_x - u_w)}{u_w}$$

where:

k = A constant, a normal value of 1,000 when the Houndsfield scale of CTN is used;
u_x= Linear attenuation coefficient of the material of interest;
u_w= Linear attenuation coefficient of water.

10. "Dose profile" means the dose as a function of position along a line.

11. "Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").

12. "Multiple tomogram system" means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

13. "Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (s_n) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{u_w}$$

where:

CS = Linear attenuation coefficient of the material of interest.
u_w = Linear attenuation coefficient of water.
s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image.

14. "Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

15. "Picture element" means an elemental area of a tomogram.

16. "Reference plane" means a plane which is displaced from and parallel to the tomographic plane.

17. "Scan" means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

18. "Scan increment" means the amount of relative displacement of the patient with respect to the CT system between successive scans measured along the direction of such displacement.

19. "Scan sequence" means a pre-selected set of two or more scans performed consecutively under preselected CT conditions of operation.

20. "Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

21. "Single tomogram system" means a CT system which obtains x-ray transmission data during a scan to produce a single tomogram.

22. "Tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

23. "Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

6-008.02 Requirements for Equipment

1. Termination of Exposure

   a. Means must be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination must occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.
   b. A visible signal must indicate when the x-ray exposure has been terminated through the means required by 180 NAC 6-008.02, item 1.a.
   c. The operator must be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT system control, of greater than one-half second duration.

2. Tomographic Plane Indication and Alignment

   a. For any single tomogram system, means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.
   b. For any multiple tomogram system, means must be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.
   c. If a device using a light source is used to satisfy the requirements of 180 NAC 6-008.02, item 2.a. or b., the light source must provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

3. Beam-on and Shutter Status Indicators and Control Switches

   a. The CT x-ray control and gantry must provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.
   b. Each emergency button or switch must be clearly labeled as to its function.

4. Indication of CT Conditions of Operation: The CT System must be designed such that the CT conditions of operation to be used during a scan or a scan sequence must be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation must be visible from any position from which scan initiation is possible.

5. Entraneous Radiation: When data is being collected for image production, the radiation adjacent to the tube port must not exceed that permitted by 180 NAC 6-004.03.

6. Maximum Surface CTDI Identification: The angular position where the maximum surface CTDI occurs must be identified to allow for reproducible positioning of a CT dosimetry phantom.

7. Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985

a. The total error in the indicated location of the tomographic plane or reference plane must not exceed 5 millimeters.
b. If the x-ray production period is less than one-half second, the indication of x-ray production must be actuated for at least one-half second. Indicators at or near the gantry must be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.
c. The deviation of indicated scan increment versus actual increment must not exceed plus or minus 1 millimeter with any mass of 0 to 100 kilograms resting on the support device. The patient support device must be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.
d. Premature termination of the x-ray exposure by the operator must necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

6-008.03 Facility Design Requirements

1. Aural Communication Provision must be made for two-way aural communication between the patient and the operator at the control panel.

2. Viewing Systems

a. Windows, mirrors, closed-circuit television, or an equivalent must be provided to permit continuous observation of the patient during irradiation and must be so located that the operator can observe the patient from the control panel.
b. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) must be available for use in the event of failure of the primary viewing system.

6-008.04 Surveys, Calibrations, Spot Checks, and Operating Procedures

1. Surveys

a. All CT x-ray systems must have a survey made by, or under the direction of, a radiological medical or health physicist meeting the requirements of 180 NAC 15-013.01 or 15-013.02. In addition, such surveys must be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

b. The registrant must obtain a written report of the survey from the radiological physicist, and a copy of the report must be made available to the Department upon request.

2. Radiation Calibrations

a. The calibration of the radiation output of the CT x-ray system must be performed by, or under the direction of, a radiological medical or health physicist.

b. The calibration of a CT x-ray system must be performed at intervals specified by a radiological medical or health physicist and after any change or replacement of components which, in the opinion of the radiological medical or health physicist could cause a change in the radiation output and at least every three years.

c. The calibration of the radiation output of a CT x-ray system must be performed with a calibrated dosimetry system. The calibration of such system must be traceable to a national standard. The dosimetry system must have been calibrated within the preceding two years.

d. CT dosimetry phantom(s) must be used in determining the radiation output of a CT x-ray system. Such phantom(s) must meet the following specifications and conditions of use:

(1) CT dosimetry phantom(s) must be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) must be at least 14 centimeters in length and must have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode.

(2) CT dosimetry phantom(s) must provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided.

(3) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters must be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(4) All dose measurements must be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

e. The calibration must be required for each type of head, body, or whole-body scan performed at the facility.

f. Calibration must meet the following requirements:

(1) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant must be measurable. Where less

than three nominal tomographic thicknesses can be selected, the dose profile determination must be performed for each available nominal tomographic section thickness.

(2) The CTDI[4] along the two axes specified in 180 NAC 6-008.04, item 2.d.(2) must be measured. The CT dosimetry phantom must be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation must correspond to typical values used by the registrant.

(3) The spot checks specified in 180 NAC 6-008.04, item 3. must be made.

g. Calibration procedures must be in writing. Records of calibrations performed must be maintained for inspection by the Department.

3. Spot Checks

a. The spot-check procedures must be in writing and must have been developed by a radiological physicist.

b. The spot-check procedures must incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

c. All spot checks must be included in the calibration required by 180 NAC 6-008.04, item 2. and at time intervals and under system conditions specified by a radiological physicist.

d. Spot checks must include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 180 NAC 6-008.04, item 2. The images must be retained, until a new calibration is performed, in two forms as follows:

(1) Photographic copies of the images obtained from the image display device; and

(2) Images sorted in digital form on a storage medium compatible with the CT x-ray system.

e. Written records of the spot checks performed must be maintained for inspection by the Department.

4. Operating Procedures

a. The CT x-ray system must not be operated except by an individual who has been specifically trained in its operation.

[4]For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

b. Information must be available in the control area regarding the operation and calibration of the system. Such information must include the following:

(1) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained.
(2) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system.
(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and
(4) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

c. If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the radiological physicist, use of the CT x-ray system on patients must be limited to those uses permitted by established written instructions of the radiological physicist.

6-009 Bone Densitometry

6-009.01 Bone densitometry systems must be:

1. Certified by the manufacturer pursuant to the Medical Device Act and Subchapter C – Electronic Product Radiation Control (EPRC) of Chapter V of the Federal Food, Drug and Cosmetic Act.; and
2. Maintained and operated in accordance with the manufacturer's specifications.

6-009.02 Equipment Requirements: Systems with stepless collimators must be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond 2 percent of the SID.

6-009.03 During the operation of any bone densitometry system the operator, ancillary personnel, and members of the general public must be positioned at least one meter from the patient and bone densitometry system during the examination.

APPENDIX 6-A
INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Department approve a healing arts screening program must submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents within this state.

2. Diseases or conditions for which the x-ray examinations are to be used in diagnoses.

3. A detailed description of the x-ray examinations proposed in the screening program.

4. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.

6. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert must show that such system(s) do satisfy all requirements of Title 180. The evaluation shall include a measurement of patient exposure from the x-ray examination to be preformed.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the x-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the x-ray system(s).

10. The qualifications of each individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation must be specified.

11. The name and address of the individual who will interpret the radiograph(s).

12. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

14. An indication of the frequency of screening and the duration of the entire screening program.

15. Documentation that supports this procedure as being of benefit to public health.

APPENDIX 6-B
INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the Department to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information must be submitted.

1. The plans should show, as a minimum, the following:

   (a) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.

   (b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

   (c) The dimensions of the room(s) concerned.

   (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

   (e) The make and model of the x-ray equipment and the maximum technique factors.

   (f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the x-ray system(s).

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, must be submitted with the plans.

APPENDIX 6-C
EXEMPTIONS FROM SHIELDING
FOR CERTAIN FLUOROSCOPIC PROCEDURES

a. Angiograms

b. Arthrograms

c. Biliary drainage procedures

d. Fluoroscopic biopsy procedures

e. Myelograms

f. Percutaneous cholangiograms

g. Percutaneous nephrostomies

h. Sinograms or fistulograms

i. T-tube cholangiograms

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Public Law 90-602
90th Congress, H. R. 10790
October 18, 1968

An Act

amend the Public Health Service Act to provide for the protection of the public health from radiation emissions from electronic products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Radiation Control for Health and Safety Act of 1968.

SHORT TITLE

SECTION 1. This Act may be cited as the "Radiation Control for Health and Safety Act of 1968".

AMENDMENTS TO PUBLIC HEALTH SERVICE ACT

SEC. 2. Part F of title III of the Public Health Service Act is amended— 58 Stat. 703; 81 Stat. 536; 42 USC 262-263a.

(1) by striking out the heading for such part and inserting in lieu thereof the following:

"PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES AND CONTROL OF RADIATION

"SUBPART 1—BIOLOGICAL PRODUCTS";

(2) by inserting immediately above the section heading of section 353 the following:

"SUBPART 2—CLINICAL LABORATORIES"; and

(3) by adding at the end of such part F the following new subpart:

"SUBPART 3—ELECTRONIC PRODUCT RADIATION CONTROL

"DECLARATION OF PURPOSE

"SEC. 354. The Congress hereby declares that the public health and safety must be protected from the dangers of electronic product radiation. Thus, it is the purpose of this subpart to provide for the establishment by the Secretary of an electronic product radiation control program which shall include the development and administration of performance standards to control the emission of electronic product radiation from electronic products and the undertaking by public and private organizations of research and investigation into the effects and control of such radiation emissions. 82 STAT. 1173 82 STAT. 1174

"DEFINITIONS

"SEC. 355. As used in this subpart—

"(1) the term 'electronic product radiation' means—

"(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

"(B) any sonic, infrasonic, or ultrasonic wave,

which is emitted from an electronic product as the result of the operation of an electronic circuit in such product;

"(2) the term 'electronic product' means (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) elec-

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ATTACHMENT 6-2

21 CFR 1020.30 and 1020.31

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(3) *Test conditions.* (i) Measurements shall be made under the conditions of use specified in instructions provided by the manufacturer.

(ii) Measurements shall be made with the tube operated under forward and reverse polarity.

(4) *Instructions, labels, and warnings.* (i) Manufacturers shall provide, or cause to be provided, with each tube to which this section is applicable, appropriate safety instructions, together with instructions for the use of such tube, including the specification of a power source for use with the tube.

(ii) Each enclosure or tube shall have inscribed on or permanently affixed to it, tags or labels, which identify the intended polarity of the terminals and:

(*a*) In the case of tubes designed primarily to demonstrate the heat effect, fluorescence effect, or magnetic effect, a warning that application of power in excess of that specified may result in the production of x-rays in excess of allowable limits; and (*b*) in the case of tubes designed primarily to demonstrate the production of x-radiation, a warning that this device produces x-rays when energized.

(iii) The tag or label required by this paragraph shall be located on the tube or enclosure so as to be readily visible and legible when the product is fully assembled for use.

§ 1020.30 Diagnostic x-ray systems and their major components.

(a) *Applicability*—(1) The provisions of this section are applicable to:

(i) The following components of diagnostic x-ray systems:

(A) Tube housing assemblies, x-ray controls, x-ray high-voltage generators, x-ray tables, cradles, film changers, vertical cassette holders mounted in a fixed location and cassette holders with front panels, and beam-limiting devices manufactured after August 1, 1974.

(B) Fluoroscopic imaging assemblies manufactured after August 1, 1974, and before April 26, 1977.

(C) Spot-film devices and image intensifiers manufactured after April 26, 1977.

(D) Cephalometric devices manufactured after February 25, 1978.

(E) Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978.

(ii) Diagnostic x-ray systems, except computed tomography x-ray systems, incorporating one or more of such components; however, such x-ray systems shall be required to comply only with those provisions of this section and §§ 1020.31 and 1020.32 which relate to the components certified in accordance with paragraph (c) of this section and installed into the systems.

(iii) Computed tomography (CT) x-ray systems manufactured before November 29, 1984.

(iv) CT gantries manufactured after September 3, 1985.

(2) The following provisions of this section and § 1020.33 are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984:

(i) Section 1020.30(a);

(ii) Section 1020.30(b) "Technique factors";

(iii) Section 1020.30(b) "CT," "Dose," "Scan," "Scan time," and "Tomogram";

(iv) Section 1020.30 (h)(3)(vi) through (h)(3)(viii);

(v) Section 1020.30(n);

(vi) Section 1020.33 (a) and (b);

(vii) Section 1020.33(c)(1) as it affects § 1020.33(c)(2); and

(viii) Section 1020.33(c)(2).

(3) The provisions of this section and § 1020.33 in its entirety, including those provisions in paragraph (a)(2) of this section, are applicable to CT x-ray systems manufactured or remanufactured on or after September 3, 1985. The date of manufacture of the CT system is the date of manufacture of the CT gantry.

(b) *Definitions.* As used in this section and §§ 1020.31, 1020.32, and 1020.33, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Accessory component means:

(1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this subchapter but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable

provisions of this subchapter but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

Aluminum equivalent means the thickness of aluminum (type 1100 alloy) [1] affording the same attenuation, under specified conditions as the material in question.

Articulated joint means a joint between two separate sections of a tabletop which joint provides the capacity for one of the sections to pivot on the line segment along which the sections join.

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Attenuation block means a block or stack of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation with dimensions 20 centimeters by 20 centimeters by 3.8 centimeters.

Automatic exposure control means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device which provides a means to restrict the dimensions of the x-ray field.

Cantilevered tabletop means a tabletop designed such that the unsupported portion can be extended at least 100 centimeters beyond the support.

Cassette holder means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film cassette during an x-ray exposure.

Cephalometric device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Coefficient of variation means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{X}} = \frac{1}{\bar{X}}\left[\sum_{i=1}^{n}\frac{(X_i - \bar{X})^2}{n-1}\right]^{1/2}$$

where:

s = Estimated standard deviation of the population.
$\bar{X}$ = Mean value of observations in sample.
X_i = ith observation sampled.
n = Number of observations sampled.

Computed tomography (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

Cooling curve means the graphical relationship between heat units stored and cooling time.

Cradle means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

(2) A device;

[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper, as given in "Aluminum Standards and Data" (1969). Copies may be obtained from: The Aluminum Association, New York, NY.

(3) For all other diagnostic source assemblies, the maximum-rated continuous tube current for the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illuminance is one-fourth of the maximum in the intersection.

Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is, Percent line-voltage regulation

$$= \frac{100\left(V_n - V_i\right)}{V_i}$$

where:

V_n = No-load line potential and
V_i = Load line potential.

Maximum line current means the root mean square current in the supply line of an x-ray machine operating at its maximum rating.

Movable tabletop means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Primary protective barrier means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

Pulsed mode means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

Quick change x-ray tube means an x-ray tube designed for use in its associated tube housing such that:

(1) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of paragraphs (k) and (m) of this section;

(2) The focal spot position will not cause noncompliance with the provisions of this section or §1020.31 or §1020.32;

(3) The shielding within the tube housing cannot be displaced; and

(4) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube housing will not result in noncompliance of the x-ray system with the applicable field limitation and alignment requirements of §§1020.31 and 1020.32.

Radiation therapy simulation system means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Rated line voltage means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

Rated output current means the maximum allowable load current of the x-ray high-voltage generator.

Rated output voltage means the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator.

Rating means the operating limits specified by the manufacturer.

Recording means producing a permanent form of an image resulting from x-ray photons (e.g., film, videotape).

Scan means the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

Scan time means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

Source means the focal spot of the x-ray tube.

Source-image receptor distance (SID) means the distance from the source to the center of the input surface of the image receptor.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of a radiograph.

Stationary tabletop means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

Technique factors means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliamperes-seconds (mAs);

(2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

(3) For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of the tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Tomogram means the depiction of the x-ray attenuation properties of a section through a body.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.

Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Variable-aperture beam-limiting device means a beam-limiting device which has the capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area means the portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

X-ray control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(1) *Mobile x-ray equipment* means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

(2) *Portable x-ray equipment* means x-ray equipment designed to be hand-carried; and

(3) *Stationary x-ray equipment* means x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray system means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray subsystem means any combination of two or more components of an x-ray system for which there are requirements specified in this section and §§ 1020.31 and 1020.32.

X-ray table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

X-ray tube means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) *Manufacturers' responsibility.* Manufacturers of products subject to §§ 1020.30 through 1020.33 shall certify that each of their products meet all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in § 1010.2 of this chapter. Manufacturers may certify a combination of two or more components if they obtain prior authorization in writing from the Director of the Office of Compliance and Surveillance of the Center for Devices and Radiological Health. Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of §§ 1020.30 through 1020.33.

(d) *Assemblers' responsibility.* An assembler who installs one or more components certified as required by paragraph (c) of this section shall install certified components that are of the type required by §§ 1020.31, 1020.32, or 1020.33 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was according to the component manufacturer's instruction.

(1) *Reports of assembly.* All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under §§ 1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§ 1020.30 through 1020.33. All assembler reports must be on a form prescribed by and available from the Director, Center for Devices and Radiological Health, 9200 Corporate Blvd., Rockville, MD 20850. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(2) *Exceptions to reporting requirements.* Reports of assembly need not be submitted for any of the following:

(i) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;

(ii) Certified accessory components that have been identified as such to the Center for Devices and Radiological Health in the report required under § 1002.10 of this chapter;

(iii) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the system was reported; or

(iv) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component

This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.
Signature
Company Name
Street Address, P.O. Box
City, State, Zip Code
Date of Installation

The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in paragraph (d)(1) of this section.

(e) *Identification of x-ray components.* In addition to the identification requirements specified in §1010.3 of this chapter, manufacturers of components subject to this section and §§1020.31, 1020.32, and 1020.33, except high-voltage generators contained within tube housings and beam-limiting devices that are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product so that they are legible and accessible to view. The word "model" or "type" shall appear as part of the manufacturer's required identification of certified x-ray components. Where the certification of a system or subsystem, consisting of two or more components, has been authorized pursuant to paragraph (c) of this section, a single inscription, tag, or label bearing the model number and serial number may be used to identify the product.

(1) *Tube housing assemblies.* In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes.* Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube housing assembly certified pursuant to paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels, that are no longer applicable.

(3) *Quick-change x-ray tubes.* The requirements of paragraph (e)(2) of this section shall not apply to tube housing assemblies designed and designated by their original manufacturer to contain quick change x-ray tubes. The manufacturer of quick-change x-ray tubes shall include with each replacement tube a label with the tube manufacturer's name, the model, and serial number of the x-ray tube. The manufacturer of the tube shall instruct the assembler who installs the new tube to attach the label to the tube housing assembly and to remove, cover, or deface the previously affixed inscriptions, tags, or labels that are described by the tube manufacturer as no longer applicable.

(f) [Reserved]

(g) *Information to be provided to assemblers.* Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and §§1020.31, 1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible. For x-ray controls and generators manufactured after May 3, 1994, manufacturers shall provide:

(1) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(2) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, he shall provide necessary information to allow the assembler to determine the

maximum line current for the particular tube housing assembly(ies);

(3) A statement of the technique factors that constitute the maximum line current condition described in paragraph (g)(2) of this section.

(h) *Information to be provided to users.* Manufacturers of x-ray equipment shall provide to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

(1) *All x-ray equipment.* For x-ray equipment to which this section and §§1020.31, 1020.32, and 1020.33 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment; and

(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§1020.31, 1020.32, and 1020.33.

(2) *Tube housing assemblies.* For each tube housing assembly, there shall be provided:

(i) Statements of the leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the tube housing assembly manufacturer states compatibility, the minimum filtration permanently in the useful beam expressed as millimeters of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;

(ii) Cooling curves for the anode and tube housing; and

(iii) *Tube rating charts.* If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self rectified, single-phase half-wave rectified, single-phase full-wave rectified, 3-phase 6-pulse, 3-phase 12-pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) *X-ray controls and generators.* For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and output current characteristics of the tube housing assembly compatible with rated output voltage and rated current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(ies);

(iii) A statement of the technique factors that constitute the maximum line current condition described in paragraph (h)(3)(ii) of this section;

(iv) In the case of battery-powered generators, a specification of the minimum state of charge necessary for proper operation;

(v) Generator rating and duty cycle;

(vi) A statement of the maximum deviation from the preindication given by labeled technique factor control settings or indicators during any radiographic or CT exposure where the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated;

(vii) A statement of the maximum deviation from the continuous indication of x-ray tube potential and current during any fluoroscopic exposure when the equipment is connected to a power supply as described in accordance with this paragraph; and

(viii) A statement describing the measurement criteria for all technique factors used in paragraphs (h)(3)(iii), (h)(3)(vi), and (h)(3)(vii) of this section; for example, the beginning and endpoints of exposure time measured with respect to a certain percentage of the voltage waveform.

(4) *Beam-limiting device.* For each variable-aperture beam-limiting device, there shall be provided;

(i) Leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the beam-limiting device manufacturer states compatibility; and

(ii) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

(i) [Reserved]

(j) *Warning label.* The control panel containing the main power switch shall bear the warning statement, legible and accessible to view:

"Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(k) *Leakage radiation from the diagnostic source assembly.* The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 2.58×10^{-5} coulombs per kilogram (C/kg) (100 milliroentgens (mR)) in 1 hour when the x-ray tube is operated at the leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(l) *Radiation from components other than the diagnostic source assembly.* The radiation emitted by a component other than the diagnostic source assembly shall not exceed 5.16×10^{-7} C/kg (2 mR) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(m) *Beam quality*—(1) *Half-value layer.* The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in table I under "Specified dental systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; and under "Other x-ray systems," for all other x-ray systems subject to this section. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in table I, linear interpolation or extrapolation may be made. Positive means[2] shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure.

TABLE I

X-ray tube voltage (kilovolt peak)		Minimum HVL (millimeters of aluminum)	
Designed operating range	Measured operating potential	Specified dental systems	Other X-ray systems
Below 51	30	1.5	0.3
	40	1.5	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

(2) *Measuring compliance.* For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

(n) *Aluminum equivalent of material between patient and image receptor.* Except

[2] In the case of a system which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlock with the kilovoltage selector which will prevent x-ray emission if the minimum required filtration is not in place.

when used in a CT x-ray system, the aluminum equivalent of each of the items listed in table II, which are used between the patient and image receptor, may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has a HVL of 2.7 millimeters of aluminum. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids.

TABLE II

Item	Aluminum equivalent (millimeters)
Front panel(s) of cassette holder (total of all)	1.0
Front panel(s) of film changer (total of all)	1.0
Cradle	2.0
Tabletop, stationary, without articulated joint(s)	1.0
Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.5
Tabletop, with radiolucent panel having one articulated joint	1.5
Tabletop, with radiolucent panel having two or more articulated joints	2.0
Tabletop, cantilevered	2.0
Tabletop, radiation therapy simulator	5.0

(o) *Battery charge indicator.* On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(p) [Reserved]

(q) *Modification of certified diagnostic x-ray components and systems*—(1) Diagnostic x-ray components and systems certified in accordance with §1010.2 of this chapter shall not be modified such that the component or system fails to comply with any applicable provision of this chapter unless a variance in accordance with §1010.4 of this chapter or an exemption under sections 358(a)(5) or 360B(b) of the Public Health Service Act has been granted.

(2) The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of §1020.31, §1020.32, or §1020.33. The owner who causes such modification need not submit the reports required by subpart B of part 1002 of this chapter, provided the owner records the date and the details of the modification, and provided the modification of the x-ray system does not result in a failure to comply with §1020.31, §1020.32, or §1020.33.

[58 FR 26396, May 3, 1993, as amended at 59 FR 26403, May 19, 1994; 64 FR 35927, July 2, 1999; 65 FR 17138, Mar. 31, 2000]

§1020.31 Radiographic equipment.

The provisions of this section apply to equipment for the recording of images, except equipment involving use of an image intensifier or computed tomography x-ray systems manufactured on or after November 28, 1984.

(a) *Control and indication of technique factors*—(1) *Visual indication.* The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(2) *Timers.* Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(i) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure

when the timer is set to a zero or off position if either position is provided.

(ii) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) *Automatic exposure controls.* When an automatic exposure control is provided:

(i) Indication shall be made on the control panel when this mode of operation is selected;

(ii) When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 milliamperes-seconds (mAs), whichever is greater;

(iii) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kW's) per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and

(iv) A visible signal shall indicate when an exposure has been terminated at the limits described in paragraph (a)(3)(iii) of this section, and manual resetting shall be required before further automatically timed exposures can be made.

(4) *Accuracy.* Deviation of technique factors from indicated values shall not exceed the limits given in the information provided in accordance with §1020.30(h)(3);

(b) *Reproducibility.* The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of §1020.30(h)(3);

(1) *Coefficient of variation.* For any specific combination of selected technique factors, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05.

(2) *Measuring compliance.* Determination of compliance shall be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation shall be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

(c) *Linearity.* The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with the requirements of §1020.30(h)(3) for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) *Equipment having independent selection of x-ray tube current (mA).* The average ratios of exposure to the indicated milliampere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is: $|X_1-X_2| \leq 0.10(X_1+X_2)$; where X_1 and X_2 are the average C/kg/mAs (or mR/mAs) values obtained at each of two consecutive tube current settings or at two settings differing by no more than a factor of 2 where the tube current selection is continuous.

(2) *Equipment having selection of x-ray tube current-exposure time product (mAs).* For equipment manufactured after May 3, 1994 the average ratios of exposure to the indicated milliampere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is:

$|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average C/kg/mAs (or mR/mAs) values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) *Measuring compliance.* Determination of compliance will be based on 10 exposures, made within ±1 hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within #1 of the mean value for all measurements at these technique factors.

(d) *Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems.* Except when spot-film devices or special attachments for mammography are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

(1) *Variable x-ray field limitation.* A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters.

(2) *Visual definition.* (i) Means for visually defining the perimeter of the x-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum SID, whichever is less. The average illuminance shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

(iii) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1 I_2, where I_1 is the illuminance 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illuminance 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 millimeter.

(e) *Field indication and alignment on stationary general purpose x-ray equipment.* Except when spot-film devices or special attachments for mammography are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in paragraph (d) of this section:

(1) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(2) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

(3) Indication of field size dimensions and SID's shall be specified in centimeters and/or inches and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

(4) Compliance measurements will be made at discrete SID's and image receptor dimensions in common clinical

use (such as SID's of 100, 150, and 200 centimeters and/or 36, 40, 48, and 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 centimeters and/or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

(f) *Field limitation on radiographic x-ray equipment other than general purpose radiographic systems*—(1) *Equipment for use with intraoral image receptors.* Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(i) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and

(ii) If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

(2) *X-ray systems designed for one image receptor size.* Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(3) *Systems designed for mammography.* (i) Mammographic beam-limiting devices manufactured after September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this section. For systems that allow changes in the SID, the SID indication specified in paragraphs (f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed.

(ii) Each image receptor support device intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(4) *Other x-ray systems.* Radiographic systems not specifically covered in paragraphs (d), (e), (f)(2), (f)(3), and (h) of this section and systems covered in paragraph (f)(1) of this section, which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(i) A system which performs in accordance with paragraphs (d) and (e) of this section; or when alignment means are also provided, may be met with either;

(ii) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(iii) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(g) *Positive beam limitation (PBL).* The requirements of this paragraph shall apply to radiographic systems which contain PBL.

(1) *Field size.* When a PBL system is provided, it shall prevent x-ray production when:

(i) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or

(ii) The sum of the length and width differences as stated in paragraph (g)(1)(i) of this section without regard to sign exceeds 4 percent of the SID.

(iii) The beam limiting device is at an SID for which PBL is not designed for sizing.

(2) *Conditions for PBL.* When provided, the PBL system shall function as described in paragraph (g)(1) of this section whenever all the following conditions are met:

(i) The image receptor is inserted into a permanently mounted cassette holder;

(ii) The image receptor length and width are less than 50 centimeters;

(iii) The x-ray beam axis is within ±3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;

(iv) The x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and

(v) Neither tomographic nor stereoscopic radiography is being performed.

(3) *Measuring compliance.* Compliance with the requirements of paragraph (g)(1) of this section shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of paragraph (g)(2) of this section are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

(4) *Operator initiated undersizing.* The PBL system shall be capable of operation such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters. Return to PBL function as described in paragraph (g)(1) of this section shall occur automatically upon any change of image receptor size or SID.

(5) *Override of PBL.* A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SID's and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

For X-ray Field Limitation System Failure

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

(h) *Field limitation and alignment for spot-film devices.* The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

(2) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not

exceed 4 percent of the SID. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(3) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

(4) Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

(i) For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square centimeters; or

(ii) For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of 5 centimeters by 5 centimeters.

(5) A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure

(i) *Source-skin distance*—(1) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

(i) Eighteen centimeters if operable above 50 kVp; or

(ii) Ten centimeters if not operable above 50 kVp.

(2) Mobile and portable x-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than 30 centimeters.

(j) *Beam-on indicators.* The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(k) *Multiple tubes.* Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated before initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

(l) *Radiation from capacitor energy storage equipment.* Radiation emitted from the x-ray tube shall not exceed:

(1) 8.6×10^{-9} C/kg (0.03 mR) in 1 minute at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square centimeters, with no linear dimension greater than 20 centimeters; and

(2) 2.58×10^{-5} C/kg (100 mR) in 1 hour at 100 centimeters from the x-ray source, with the beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum exposure per discharge multiplied by the total number of discharges in 1 hour (duty cycle). The measurements shall be averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(m) *Primary protective barrier for mammography x-ray systems.* For mammography x-ray systems manufactured after September 30, 1999:

(1) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross

section of the useful beam along every direction except at the chest wall edge.

(2) The x-ray tube shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in paragraph (m)(1) of this section.

(3) The transmission of the useful beam through the primary protective barrier shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the primary protective barrier does not exceed $2.58X10^{-8}$ C/kg (0.1 mR) for each activation of the tube.

(4) Compliance for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at the maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

[58 FR 26401, May 3, 1993; 58 FR 31067, May 28, 1993, as amended at 64 FR 35927, July 2, 1999]

§ 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopy and for the recording of images through an image intensifier except computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Primary protective barrier*—(1) *Limitation of useful beam.* The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier if provided, shall not exceed 3.34×10^{-3} percent of the entrance exposure rate, at a distance of 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in § 1020.30(g). Additionally, the manufacturer shall provide to users, pursuant to § 1020.30(h)(1)(i), precautions concerning the importance of remote control operation.

(2) *Measuring compliance.* The entrance exposure rate shall be measured in accordance with paragraph (d) of this section. The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(b) *Field limitation*—(1) *Nonimage-intensified fluoroscopy.* (i) The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of the field size. The minimum field size, at the greatest SID, shall be containable in a square of 5 centimeters by 5 centimeters.

(ii) For equipment manufactured after February 25, 1978, when the angle between the image receptor and the